

Spironolactone and exercise capacity in older people

Submission date 07/08/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/11/2017	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Many older people find that they become less strong as they get older, and that this loss of strength interferes with the ability to everyday activities. Loss of strength with age also leads to falls, broken bones, and the need for more help with daily activities. Although exercise works well to improve muscle strength and function even in older people, not everyone can, or wants to, exercise. Finding medications that can improve muscle function may provide an alternative way of treating this problem. Spironolactone is a medicine used to treat heart failure and high blood pressure. There is some evidence that it might have directly beneficial effects on muscle function – separate from its effects on blood pressure or the heart. This idea has not been tested before, and the aim of this study is to test whether spironolactone increases exercise capacity in functionally impaired older people without chronic heart failure.

Who can participate?

People aged 65 and over who have problems with daily living activities

What does the study involve?

Participants are randomly allocated to take either spironolactone or placebo (dummy) capsules for 5 months. Participants visit the hospital three times over the 5 months. Each visit lasts between one and two hours. At each visit, participants perform some walking tests and complete three questionnaires about how much they are able to do and how they feel. They provide details of what medicines they are taking, their blood pressure is measured and blood samples are taken (no more than a few teaspoonfuls). At the start of the study, participants undergo an echocardiography (ultrasound) scan of their heart.

What are the possible benefits and risks of participating?

Spironolactone is a diuretic drug therefore participants may pass more urine than usual. Spironolactone has been used as a medication for 60 years and is safe. However, it can occasionally cause an upset stomach, dizziness or breast enlargement. It can also increase blood potassium levels, lower sodium levels, or interfere with kidney function in some people. Blood results are closely monitored throughout the study and if any of these problems are detected, participants are taken off the medication. These problems almost always disappear on stopping the medication. The blood tests may cause some minor discomfort. Although participants are

unlikely to benefit directly by taking part, those who receive the spironolactone might improve your muscle function and exercise capacity, making them feel stronger.

Where is the study run from?
Ninewells Hospital & Medical School (UK)

When is the study starting and how long is it expected to run for?
October 2008 to April 2011

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Marion McMurdo

Contact information

Type(s)
Scientific

Contact name
Prof Marion McMurdo

Contact details
Section of Ageing & Health
Division of Medicine & Therapeutics
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

Additional identifiers

Clinical Trials Information System (CTIS)
2008-002373-12

Protocol serial number
CZB/4/635

Study information

Scientific Title
Effect of spironolactone on exercise capacity in older people without heart failure: a double-blind placebo-controlled trial

Study objectives
Inhibition of the renin angiotensin aldosterone system with spironolactone will improve exercise capacity in older people without heart failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Tayside Committee of Medical Research Ethics, 06/08/2008, ref: 08/S1402/34

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Decline in physical function with age

Interventions

Spironolactone 25 mg once daily or placebo once daily for a period of 20 weeks.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Spironolactone

Primary outcome(s)

Change in six minute walking distance over 20 weeks from baseline

Key secondary outcome(s)

Change in the following from baseline to 20 weeks:

1. Time taken to perform the timed get up and go test
2. EuroQol 5D (-0.59 to 1.0) and Visual Analogue Scale (0 - 100)
3. Functional Limitation Profile Scale
4. Hospital Anxiety and Depression Scale (anxiety 0 - 21; depression 0 - 21)
5. Incremental shuttle walk test (time and distance)

Completion date

01/04/2011

Eligibility

Key inclusion criteria

1. Aged 65 years and over, either sex
2. Self-reported problems with activities of daily living

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. A clinical diagnosis of symptomatic heart failure according to the Economic and Social Research Council (ESRC) criteria
2. Asymptomatic left ventricular systolic dysfunction
3. Already taking spironolactone
4. On angiotensin converting enzyme inhibitor or angiotensin receptor blocker
5. Systolic blood pressure less than 100 mmHg
6. Serum potassium greater than 5.0 mmol/l
7. Serum sodium less than 130 mmol/l
8. Creatinine greater than 200 umol/l
9. Estimated glomerular filtration rate (eGFR) less than 30 ml
10. Addison's disease
11. Previous reported intolerance of spironolactone
12. Cognitive impairment precluding informed consent
13. Wheelchair bound
14. Unwilling to participate

Date of first enrolment

01/11/2008

Date of final enrolment

01/11/2010

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Ninewells Hospital & Medical School

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office (ref: CZB/4/635)

Alternative Name(s)

CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Study data are available on request from Dr Catrina Forde (c.forde@dundee.ac.uk) for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee).

Participant consent for unrestricted sharing of individual participant data was not obtained

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No

[Basic results](#)

24/10/2017

20/11/2017

No

No